

Notice of Allowability

Application No.

09/585,431

Applicant(s)

BELLEAU ET AL.

Examiner

Art Unit

Raymond J. Henley III

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed June 29, 2005.
2. ☒ The allowed claim(s) is/are 1-18.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 08/084,222.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material

5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413B)
Paper No./Mail Date 7/29/05
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

RAYMOND HENLEY III
PRIMARY EXAMINER

441417

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EXAMINER'S AMENDMENT

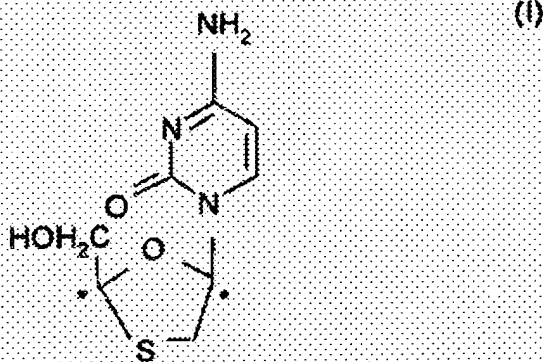
An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The amendments below are being made solely for the purpose of placing claims 10, 12 and 15-18 in proper amendatory format, (see 37 CFR 1.173(b)(2)).

The application has been amended as follows:

Claim 10 now appears as:

10. (Currently Amended) A method for the treatment of hepatitis B infection, in a human, suffering from hepatitis B infection, comprising administering to said human an effective amount of a compound of formula (I)

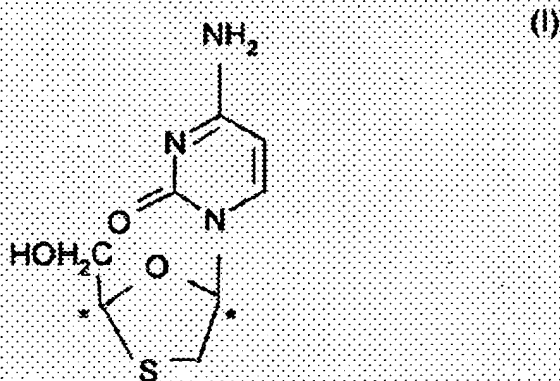


or a pharmaceutically acceptable salt, ester, or salt of an ester thereof.

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Claim 12 now appears as:

12. (Currently Amended) A method for the treatment of hepatitis B infection, in a human, suffering from hepatitis B infection, comprising administering to said human an effective amount of a compound of formula (I)



or a pharmaceutically acceptable salt thereof.

Claim 15 now appears as:

15. (Currently Amended) The method according to claim 13, comprising administering (-)-cis-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one.

Claims 16 and 17 now appear as:

16. (New) The method according to claim 11, wherein the (-)-cis-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one or pharmaceutically acceptable salt thereof is substantially free of the corresponding (+)-enantiomer.

17. (New) The method according to claim 13, wherein the (-)-cis-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one or pharmaceutically acceptable salt thereof is substantially free of the corresponding (+)-enantiomer.

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Claim 18 now appears as:

18. (New) The method according to claim 15, wherein the (-)-cis-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one is substantially free of the corresponding (+)-enantiomer.

Attached Form PTO-892

The Kassianides et al. reference cited on the attached form PTO-892 was cited during prosecution of Applicants' U.S. Patent No. 5,532,246. It was omitted from the form PTO-892 mailed March 29, 2005 and is now being cited in order to complete the listing of references cited. A copy of this reference has not been included with this action.

Supplemental Reissue Declaration

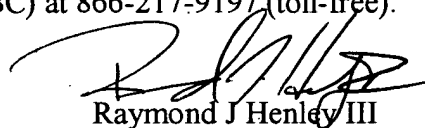
Applicants' Supplemental Reissue Declaration filed by facsimile on July 20, 2005 has been received and entered into the application. See the attached Examiner-Initiated Interview Summary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Raymond J Henley III
Primary Examiner
Art Unit 1614

July 8, 2005

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